

## Standard Operating Procedure (SOP)

# USE OF UHBW CRF SLEEP STUDIES SUITE

<b>SETTING</b>	Trust-wide
<b>FOR STAFF</b>	All staff wishing to use the UHBW CRF Sleep Studies Suite
<b>ISSUE</b>	Use of CRF for both research and non-research purposes.

## Standard Operating Procedure (SOP)

### Document History

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N/A	V1.0	25/JAN/2021	26/FEB/2021	Jess Bisset Elinor Griffiths	Diana Benton on behalf of Trust Research Group

### 1. Introduction

In the UHBW Clinical Research Facility (CRF) is a Sleep Studies Suite (SSS) which comprises of a foyer area, control room and two bedrooms each with an en-suite bathroom (see Figure A). Where a request has been made to use the Suite in line with SOP\_025 *Applying for use of the UHBW CRF*, this SOP covers the local rules and procedures which must be followed. This applies to the use of the SSS in normal working hours (9am-5pm) and outside of working hours (5pm-9am).

### 2. Purpose

This SOP sets out the conditions of use of the Sleep Studies Suite at the UHBW CRF to ensure safety of participants and staff.

### 3. Scope

**In Scope:** Use of the Sleep Studies Suite at the UHBW CRF for sleep studies.

**Out of Scope:** Use of the Clinical Investigation Suite and other rooms at UHBW CRF. See SOP\_025 *Applying for use of the UHBW CRF* and associated documents for further information on use of those rooms. Use of the SSS during normal working hours for non-sleep studies (i.e. as clinic rooms).

### 4. Responsibilities

- Research staff who have been authorised to use the Sleep Studies Suite are responsible for ensuring they do so in accordance with this SOP, applicable research approvals, local UHBW procedures and policies and TMPL101 Agreement For Use of CRF.
- The CRF Management Group (CMG) are responsible for oversight of use of the Sleep Studies Suite at the CRF.
- Further responsibilities can be found in section 6.5 below

### 5. Abbreviations and Definitions

Abbreviations	
CRF	Clinical Research Facility
CMG	CRF Management Group
HRA	Health Research Authority
MA	Management Assistant
REC	Research Ethics Committee
R & I	Research and Innovation
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
Definitions	
Out of hours	5.00pm-9.00am and includes weekends (all hours of Saturday and Sunday).

### 6. Procedure

#### 6.1 Responsible Authorised User (RAU)

When use of the CRF has been authorised by the CRF Management Group (CMG) see SOP\_025 *Applying for use of UHBW CRF* and that use involves the SSS, one of the researchers will be identified as the Responsible Authorised User (RAU). The RAU will undertake both the CRF building induction and the SSS induction and will take overall responsibility for the safety of staff and participants in the overnight studies as described in more detail below.

## 6.2 Booking procedure

In line with SOP\_025 *Applying for use of UHBW CRF*, when agreement for use of the SSS has been made researchers must first register as a user on Calpendo (if not done so already). When the researcher has been approved as a user, they can then register their project on Calpendo by entering their project details in the 'create project' section. When booking sleep rooms using the Calpendo system, researchers need to book the study over the whole night. This involves booking the evening up to midnight on the first day and then from midnight to 9am on the second day.

The CRF MA must then contact the appropriate security services at UHBW and provide the following details:

- Date and time of overnight study
- Name and contact details of Responsible Authorised User (RAU) and all research personnel present during overnight study
- Total number of persons present for overnight study

## 6.3 Access to the SSS

In line with 6.2 once authorised to use the SSS and after the applicable bookings have been made on Calpendo the Management Assistant (MA) at the CRF will liaise with the researcher to provide access. The SSS is accessed by swipe card only and the control room is accessed by fob and contains the video monitoring and recording equipment.

The MA will request swipe card access for UHBW staff cards; external personnel will be given a UHBW CRF swipe card which must be collected with the fob and any necessary keys (for any additional rooms booked) and signed for during normal working hours (9am-4pm) before commencing the overnight study. The swipe card, fob and any keys must then be returned to the MA (again during normal working hours) who will sign back in. Internal UHBW employees will also need to sign the fob and keys out and back in upon their return to the MA.

The swipe card, fob and keys must only be used by authorised personnel and kept safely for the duration of use. The MA will keep a log of the loan any swipe cards, fob and keys and ensure they are returned.

## 6.3 Emergencies

### 6.3.1 Medical emergency

If there is a medical emergency requiring the resuscitation team the following should be carried out:

## Management of CARDIORESPIRATORY ARREST (or other medical emergency)

***There should always be at least two people present when conducting research studies at the CRF.***

	Person 1	Person 2
1	Commence CPR immediately	Dial 2222 to call the Resuscitation Team
2		Clearly state which team you need, i.e. adult, paediatric or neonatal
3		State that access to CRF is via the corridor on level B, St Michael's Hospital
4		Take the appropriate, resuscitation trolley, i.e. combination or neonate, to the scene
5		Wait at entry to CRF on the level B corridor to direct the Resuscitation Team
6		Assist with resuscitation as appropriate

***Following the resuscitation, the leader of the resuscitation team will be responsible for the post-resuscitation care & safe transport of the patient***

### 6.3.2 Security emergency

If the researcher is under threat or needs security on site they should call **0117 34 2222** and request security assistance. In case of life threatening emergency call the police on **999**

### 6.3.3 Fire emergency

During overnight studies the RAU is the acting fire warden and is responsible for ensuring that everyone has exited the building

In the event of a fire within the CRF, the alarm should be raised using the RED fire alarm boxes located next to every fire door and all staff, research participants and visitors should be evacuated in line with UHBW policy.

The RAU must familiarise themselves with the fire evacuation procedure below.

### Fire evacuation procedure

- (i) Immediately call the Fire Service via Security emergency 0117 34 2222. The nearest fire escape to the assembly point is the CRF main entrance.

In the event of a fire:

- swipe card panels for all swipe access doors are disabled, so these doors can be used without restriction
- the fire resistant doors along the two main CRF corridors will automatically shut
- the front doors to the CRF will open automatically and will stay open for the duration of time that the fire alarm sounds, as this is a fire escape

- (ii) If the fire is in the Sleep Study Suite, the RAU should attempt to cut off the medical gases

supply if it is safe to do so. The medical gases cut off are found in the corridor that the SSS is on, and are clearly marked on the Sleep Studies Suite floor plan in Annex 1. The CRF MA will show the RAU the location of the medical gases cut off before the study commences as part of the RAU induction to the unit.

- (iii) The nearest fire extinguishers are located in the corridor to the left of the SSS.
- (iv) Smoke detectors are fitted in all rooms of the SSS. If the fire alarms in the building sound with a continuous ring, the SSS should be evacuated even if no fire is evident. Assemble at the designated Assembly Point which, for the CRF, is beyond the main entrance on the pavement of St Michael's Hill by the CRF sign and wait for permission to re-enter the building.
- (v) If a fire occurs outside normal working hours, the Fire Service should be met by a RAU at the Fire designated Assembly Point for the CRF.
- (vi) All incidents must be reported to the CRF MA and on the UHBW Datix system.

#### **6.4 After study completion**

After a study has been completed, please write in the diary log in the control room the following:

- The name of the study
- The researchers that attended the study
- Any information about the study; problems etc.
- The consumables/equipment used who it was /is going to be cleaned by and if anything needs re-ordering.\*

*\*If equipment needs ordering or if something is broken please inform the CRF MA to make sure that new supplies are ordered.*

#### **6.5 Responsibilities**

##### **6.5.1 Responsibilities of the Responsible Authorised User (RAU)**

- The RAU is responsible for booking the SSS and providing the names of all other researchers, participant(s), and persons occupying SSS for their overnight study.
- The RAU is responsible for following UHBW procedures for the health and safety of the researchers, participants and other persons present in their overnight study.
- The RAU is responsible for signing in and out all researchers, participants and all other persons who will be present in their overnight study in the sign in book located in reception.
- The RAU assumes the responsibility of fire warden during the overnight study
- Minimum staffing for overnight studies is two researchers. Therefore, if during the overnight study one of the two researchers needs to leave the CRF for any reason, a replacement researcher must attend prior to their departure. If this is not possible, the overnight study must be terminated and all participants and researchers must vacate the CRF.

##### **6.5.2 Responsibility of UHBW CRF**

For the protection of researchers the CRF has CCTV installed. All CCTV recordings are not monitored but are recorded and stored for a maximum of 1 week.

### **6.5.3 Entrance and exit**

For overnight studies (i.e. out of office hours 5pm-9am) access to the CRF is via the St Michael's Hospital main entrance on Southwell Street. Entry to and exit from the CRF for researchers and participants is via the Level-B corridor of St Michael's Hospital. In the CRF, the door between the CRF and St Michael's Hospital is at the far end of the corridor on which the SSS is located.

During overnight studies, the CRF main entrance is to be used as an Emergency Fire Exit ONLY and not as an entrance and exit. There is an intercom system in the sleep control room that allows researchers to open the main doors without leaving the room. DO NOT use this system out of working hours; only use the entrance via St Michael's Hospital.

The RAU will be required to arrive at 5pm and complete their duties and secure the building on weekdays by 9am. From 9am, responsibility for securing the building will be taken by CRF daytime staff .

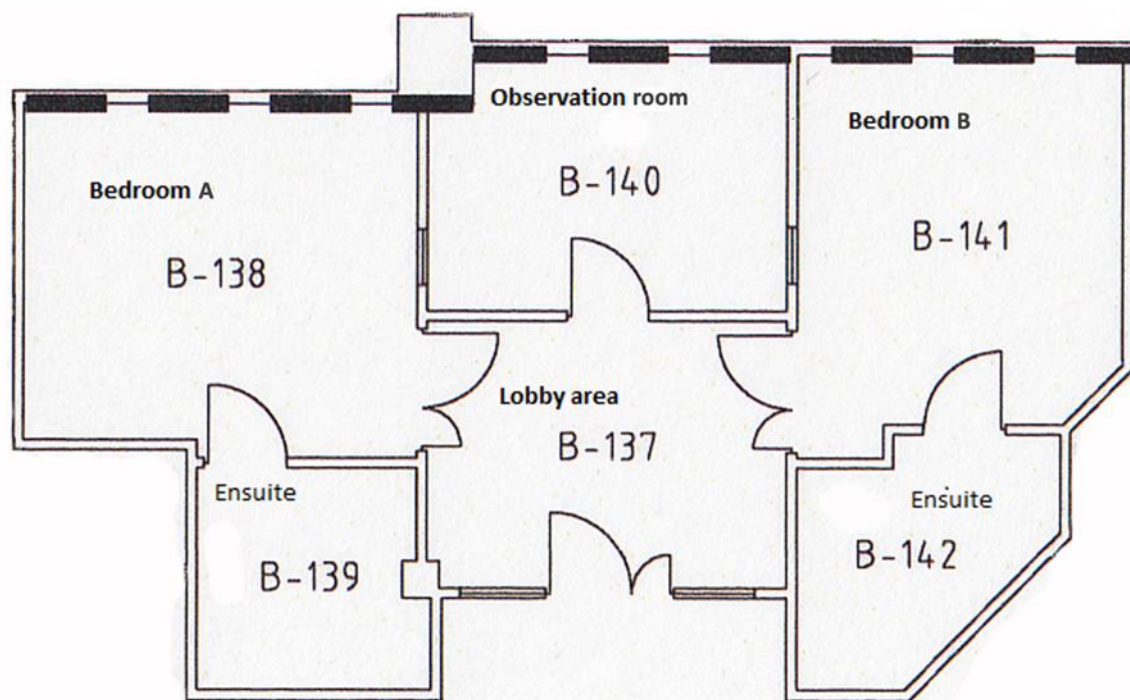
When the overnight study is complete the RAU is responsible for ensuring that everyone has exited the building before setting the security alarm system.

## **7. Dissemination and training in the SOP**

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP 007 Research Training*.

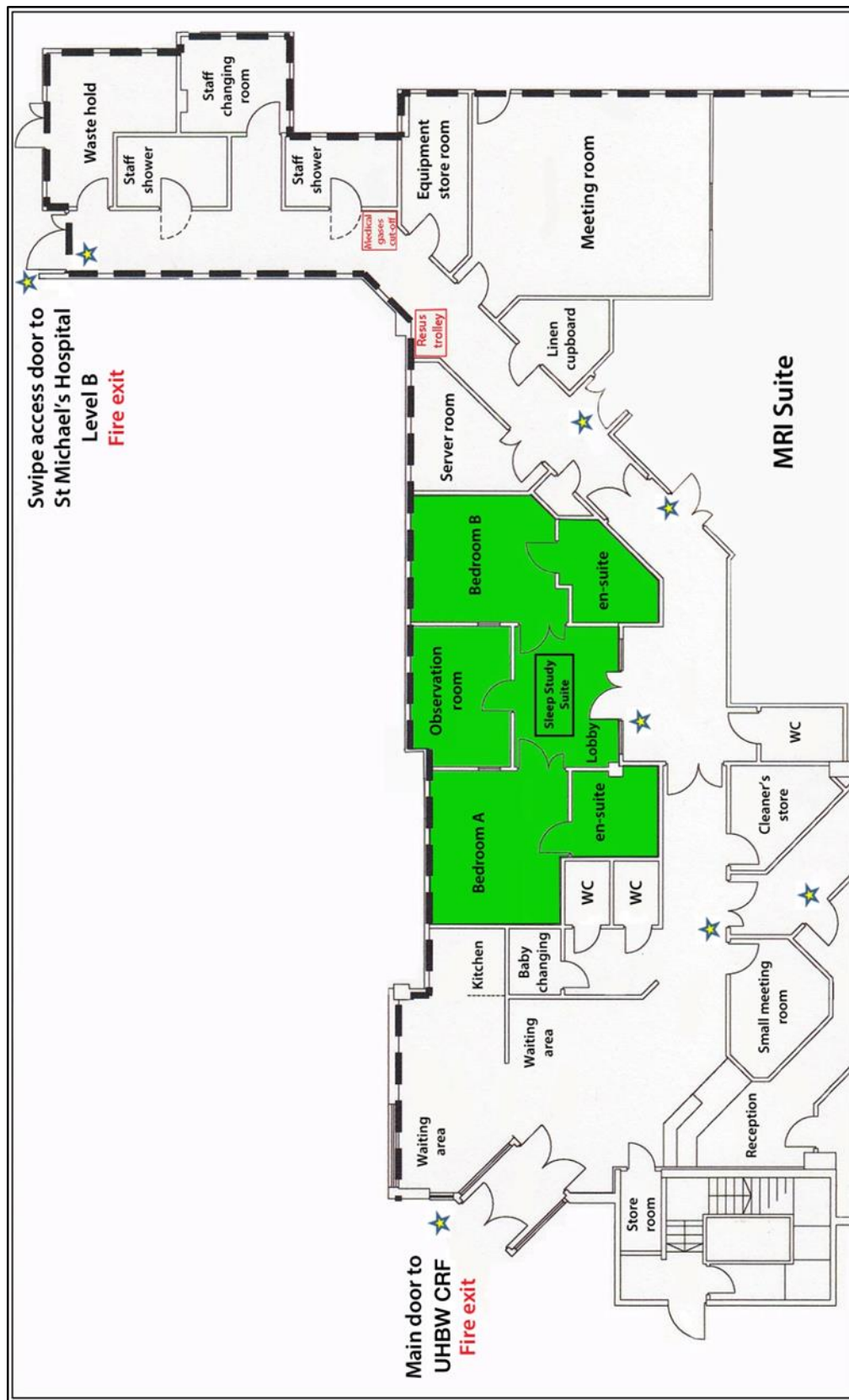
Figure A – SSS layout



Sleep study suite, UHBW CRF



## Annex 1: SSS Floor plan





**Table A**

<b>REFERENCES</b>	
<b>RELATED DOCUMENTS AND PAGES</b>	SOP_025 Applying for use of UHBW CRF TMPL_100 Request use of CRF Form
<b>AUTHORISING BODY</b>	Trust Research Group
<b>SAFETY</b>	All staff making use of the clinical research facility must complete the building induction which provides information and signposting towards safety documents including MRI fire procedures and MRI quenching.
<b>QUERIES AND CONTACT</b>	Please contact the Research & Innovation department via <a href="mailto:CRF@uhbw.nhs.uk">CRF@uhbw.nhs.uk</a>